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No. 87-17

Supreme Court, U.S.
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JOSEPH F. SPANIOL, JR.
CLERK

In The

Supreme Court of the United States

October Term, 1986

—o—

STEPHEN COWAN, CHESTER DUPONT, LORNA

PURKEY and FREDERICK S. MAYER

Petitioners,

JUL 29 1987

JOSEPH F. SPANIOL, JR.
CLERK

vs.

BEVERLEE A. MEYERS, Acting Director, Department of Health Services, State of California; KENNETH KIZER, Director, Department of Health Services, State of California; DEPARTMENT OF HEALTH SERVICES, State of California; GRAY DAVIS, Controller, State of California; and JESSE UNRUH, Treasurer, State of California,

Respondents.

—o—

On Writ of Certiorari to the Court of Appeal,
State of California, Third Appellate District

—o—

BRIEF FOR RESPONDENTS IN OPPOSITION

—o—

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STATEMENT OF THE CASE

On May 31, 1983, the Superior Court in and for the
County of Sacramento issued an order which in effect
promulgated a new and dramatically different Medi-Cal¹
program for the State of California.

First, the Superior Court redefined and broadened the
definition of the term "medical necessity." This term is

1. Medi-Cal is California's name for its Medicaid program.

crucial to the provision of Medi-Cal benefits because only medically necessary benefits are provided and funded.

The trial court, in essence, held that the new definition of "medical necessity" found in California Welfare and Institutions Code section 14133.3 illegally interfered with the relationship between the recipient-patient and the physician in that it allowed the Department of Health Services to define medical necessity and did not defer solely to the physician's determination.

The trial court also held that the section 14133.3 definition was illegal because it was inconsistent with the objectives of the federal Medicaid Act in that the services provided were insufficient in amount, duration and scope to reasonably achieve their purposes.

The trial court so held in spite of the fact that the federal government had approved California's new definition of medical necessity.

The superior court's second major revision of the Medi-Cal program was the elimination of all prior authorization. Prior authorization (implemented through documents called "treatment authorization requests" or "TARS") is that scheme which requires certain benefits to be approved by Medi-Cal *before* they are provided to the recipient. This prior authorization system has long existed in California and has been long approved by the federal government. This system works both as a utilization control (i.e., a guard against abuse) and a guarantee (i.e., if a provider obtains a TAR, he is assured of reimbursement by Medi-Cal). Proper utilization controls are

required by the federal government before it will participate, by way of funding, in a state Medicaid plan.

The TAR system attempts to insure that only medically necessary services are provided and funded. All services are not subject to TARS. Only certain services require a TAR approval. TARS are submitted by the provider to DHS whose medical professionals review them for approval. DHS medical professionals work through personnel trained to evaluate TARS. The staff can review TARS submitted on written form or by telephone. An appropriate medical professional is available to discuss TARS with providers, i.e., DHS pharmacists are available to consult with provider pharmacists, etc. The time for TAR approval is routinely a matter of a few days and immediate telephone approval is possible. During the non-working hours, services can be provided without TARS and will be funded if appropriate. Similarly, in emergencies, services can be provided without TARS and will be funded if an emergency existed. Every effort, within the confines of fiscal limitations, is made to insure prompt, efficient, intelligent responses to TARS.

The trial court held that the TAR system (which was required and approved by the federal government) illegally interfered with the relationship between the recipient-provider and physician. The trial court also held that the TAR system was fatally inconsistent with the federal Medicaid Act.

In its opinion, the District Court of Appeal for the Third District corrected both errors committed by the trial court, to wit: The definition of "medical necessity" was held to have been correctly promulgated by the state as a

“macro-decision” and the prior authorization system utilized by California was held to be legal and proper. This opinion was not disturbed by the Supreme Court of California, nor should this Court grant the Petition for Writ of Certiorari.

SUMMARY OF ARGUMENT

The petition seeks to disturb a correct statement of the law by the California District Court of Appeal regarding the definition of “medical necessity” and utilization controls within the Medi-Cal System. The California District Court of Appeal correctly set forth applicable federal and state law in holding that neither California’s definition of “medical necessity” nor its utilization control system violates the Social Security Act of 1965.

ARGUMENT

I

THE CALIFORNIA STATE COURTS CORRECTLY DETERMINED THAT CALIFORNIA’S DEFINITION OF MEDICAL NECESSITY IS CONSISTENT WITH FEDERAL LAW

The appellate court correctly held that California’s definition of medical necessity was consistent with federal law.

For this Court's convenience, Welfare and Institutions Code section 14133 (as it then read) will be set forth in full here:

“(a) The director shall require fully documented medical justification from providers that the requested services are medically necessary or protect life or prevent significant disability, on all requests for prior authorization.

“(b) For services not subject to prior authorization, the director shall additionally determine utilization controls which shall be applied to assure that the health care services provided and the conditions treated, are medically necessary to protect life or prevent significant disability. Such utilization controls shall take into account those diseases, illnesses, or injuries which require preventive health services, or treatment to prevent serious deterioration of health.

“(c) Nothing in this section shall preclude payment for family planning services, early or periodic screening, diagnosis and treatment services mandated by federal law.”

The trial court had incorrectly held that California's definition was twice flawed: (1) the definition was an interference with the relationship between the recipient-patient and physician (or other medical professional); and (2) the definition was inconsistent with the objectives of the Medicaid Act, Title XIX of the Social Security Act of 1965, at 42 U.S.C. 1396a et seq. The trial court's holdings on both points were erroneous. The trial court's incorrect rulings were based upon an erroneous reading of *Pinneke v. Preisser* (8th Cir. 1980) 623 F.2d 546; *Preterm, Inc. v. Dukakis* (1st Cir. 1979) 591 F.2d 121, and other related cases.

**A. The Appellate Opinion Correctly Held That
The Physician Is Not The Sole Arbiter Of
Medical Necessity**

In *Preterm*, the appellants had sought an injunction to prohibit enforcement of a Massachusetts statute which permitted public funding of abortions only to prevent the death of the mother and in cases where an abortion was necessary for the proper treatment of victims of forced rape or incest. The United States Court of Appeals for the First Circuit held, inter alia, that a state may not discriminate against a specific medical condition (abortion) by utilizing a more stringent definition of medical necessity for its treatment than for other medical conditions. Massachusetts could not utilize one definition of medical necessity for all medical conditions except abortions and utilize a different, more exclusionary, definition of medical necessity as a threshold to funding abortions. (*Preterm, Inc. v. Dukakis, supra*, 591 F.2d at 126.) California, on the other hand, uses a single standard.

Moreover, *Preterm* teaches that the decision as to what is a medical necessity is a two-step analysis. Generally, the state Legislature promulgates a statute which determines which types of medical assistance are included within its plan and which types are not (a "macro-decision"). Specifically, the physician determines whether a type of included assistance is medically necessary to his patient (a "micro-decision"). (*Id.* at 125.)

In the instant case, the trial court incorrectly relied on *Preterm* to support its ruling that a patient's physician is the sole arbiter of medical necessity, thus leading to the conclusion that the state and its taxpayers must pay for

any medical assistance a physician determined as medically necessary. This would inevitably lead to a high level of medical coverage that, it is safe to speculate, most taxpayers would deny even themselves.

The appellate court correctly read *Preterm* and concluded that, as a matter of law, the physician is not the sole arbiter of medical necessity. The physician decides only which of the legislatively predetermined coverages are medically necessary to the patient, not the total scope of coverage.

The trial court's reliance on *Pinneke v. Preisser*, *supra*, 623 F.2d 546 was also misplaced. Citing *Pinneke*, the trial court opined that the physician was the sole arbiter of medical necessity. This plainly erroneous reading of the decision was rectified by the Appellate Court.

In *Pinneke*, the recipient-patient sought sex reassignment surgery, which was refused as not medically necessary. Pinneke was diagnosed as a female personality within a male body. Sex reassignment surgery was established as the only treatment for this condition. The surgery was determined to be medically necessary by her physician. (*Pinneke v. Preisser*, *supra*, at 547-548.) The appellate court ordered, inter alia, public funding for the surgery.

The Iowa Department of Social Services had established, without formal rule-making proceedings or hearings, an *irrebuttable* presumption that the sex reassignment surgery could *never* be medically necessary. The appellate court stated that the irrebuttable presumption (promulgated informally) reflected an "inadequate solicitude for [Pinneke's] diagnosed condition, the treatment prescribed

by [Pinneke's] physicians, and the accumulated knowledge of the medical community." (*Pinneke v. Preisser, supra*, at 549.)

The court went on to hold:

" . . . Congress intended medical judgments to play a primary role in the determination of medical necessity. [Citations omitted.]

"The decision of whether or not certain treatment or a particular type of surgery is 'medically necessary' rests with the individual's physician and not with clerical personnel or government officials. And as stated in *White v. Beal* (3rd Cir. 1977) 555 F.2d 1146 'The regulations permit discrimination in benefits based upon the degree of medical necessity but not upon the medical disorders from which the person suffers.' " (*Pinneke v. Preisser, supra*, 623 F.2d at 550.)

Clearly, in the instant case, the trial court misapplied the holding in *Pinneke*. The *Pinneke* court, much like the *Preterm* court, held that a specific medical condition cannot be discriminated against by the use of a definition of medical necessity which effectively precludes any treatment for that condition. The *Pinneke* court also held that it is permissible for a state to promulgate regulations which limit benefits, across the board, based upon a more stringent definition of medical necessity.

In sum, the trial court misinterpreted pertinent case law. The Court of Appeal properly corrected this misinterpretation. The Court correctly held that the physician is not the sole arbiter of medical necessity and that the Medicaid statutes and regulations permit a state to define medical necessity in a way tailored to the requirements of its own Medicaid program.

In reaching this conclusion, the Court of Appeal correctly read *Rush v. Parham* (5th Cir. 1980) 625 F.2d 1150. In *Rush*, plaintiff brought suit to compel the state to pay for her transsexual surgery, which the state had refused to do. Rush claimed the refusal violated the federal Medicaid Act. Rush's physician had determined that the transsexual surgery was medically necessary. The state had refused funding on two bases: (1) the surgery was "experimental," and (2) the surgery, in the opinion of the state, was inappropriate treatment for Rush. Rush moved for summary judgment on two grounds: (1) the state could not, as a matter of law, deny funding for a service which two private physicians had deemed, in their judgment, to be medically necessary, and (2) the state, as a matter of law, had abused its discretion by determining that transsexual surgery was inappropriate treatment for Rush. The trial court granted Rush's motion, holding that the state must pay for all medically necessary services of Medicaid recipients and that the determination of Rush's physician that transsexual surgery was medically necessary could suffer no interference from the state. The Circuit Court of Appeals reversed and remanded.

Pertinent here, the *Rush* court specifically held that, ". . . a state Medicaid agency can review the medical necessity of treatment prescribed by a doctor on a case-by-case basis." The court's language is illuminating:

"The district court has, in effect, held that a state has no role in determining whether a particular service is medically necessary. In our view, however, the Medicaid statutes and regulations permit a state to define medical necessity in a way tailored to the requirements of its own Medicaid program. Our analysis begins with the statute, which provides that:

“A State plan for medical assistance must . . . include reasonable standards . . . for determining eligibility for and the extent of medical assistance under the plan which . . . are consistent with the objectives of this [title].

“42 U.S.C. § 1396a(a)(17) (1976). The Supreme Court has interpreted this language as conferring broad discretion on the States to adopt standards for determining the extent of medical assistance, requiring only that such standards be ‘reasonable’ and ‘consistent with the objectives’ of the Act. *Beal v. Doe*, 432 U.S. 438, 444, 97 S.Ct. 2366, 2371, 53 L.Ed.2d 464 (1977). Under the district court’s decision, however, the states would only have discretion to exclude from coverage the so-called optional services listed in sections 1396(a)(6)-(17). The general language of section 1396a(a) suggests that Congress intended the states’ discretion to be considerably less circumscribed.

“The key to defining the states’ role in determining the extent of coverage can be found in the Supreme Court’s use of the word ‘standard’ in the passage we quoted from *Beal v. Doe*. We think the Court was saying that a state may establish standards for individual physicians to use in determining what services are appropriate in a particular case. This state responsibility to establish standards extends at least to the shaping of a reasonable definition of medical necessity. The Department of Health and Welfare regulations so provide: ‘The [state] agency may place appropriate limits on a service based on such criteria as medical necessity. . . .’ (42 C.F.R. § 440.230(d).)

“This does not remove from the private physician the primary responsibility of determining what treatment should be made available to his patients. We hold only that the physician is required to operate within such reasonable limitations as the state may impose. This same relationship between the private physician and government exists in the federal Medi-

care program, which, like Medicaid, is centered around the judgment of the private physician. See 42 U.S.C. § 1396a(a)(23) (1976) (Medicaid recipients permitted freedom of choice in selecting a physician) and 42 U.S.C. § 1395a (1976) (similar Medicare provisions).” (*Rush v. Parham, supra*, 625 F.2d at 1155-1156.)

Rush teaches that treatment funded by Medicaid is a cooperative, bilateral exercise between the physician and the state (including its taxpayers) who pay the bills. The Appellate Court correctly ruled that Medicaid treatment was not a unilateral endeavor by the physician.

B. Federal Medicaid Regulations Permit California To Define Medical Necessity.

The Appellate Court held that California’s definition of medical necessity was consistent with the objectives of the federal Medicaid Act. This holding should not be disturbed, it is correct as a matter of law. 42 C.F.R. section 440.230 permitted California to define the term “medical necessity.” 42 C.F.R. section 440.230 provided in pertinent part:

“(c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.

“(d) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.”

The trial court relied specifically on subsections (a)(2)(b) and (a)(2)(c) to contend that the state plan, as embodied in section 14133.3, is fatally inconsistent with federal Social

Security Law. The trial court was wrong. Subsection (a)(2)(d) authorized states to “. . . place appropriate limits on a service based on such criteria as medical necessity. . . .”

By adopting section 14133.3, California placed a limit on services by redefining medical necessity. Section 14133.3 defined medical necessity as a medical service required “. . . to protect life or prevent significant disability . . .” The showing of a medical necessity triggered the provision of services. California previously provided medical services, “as medically necessary.” (22 Cal. Admin. Code, § 5100(E).)

The New Jersey Supreme Court ruled that such limitations are lawful and consistent with the Social Security Act. (*Dougherty v. Human Services Dept.* (91 N.J. 1, 1982) 449 A.2d 1235.) In *Dougherty*, medical assistance, in the form of the purchase price (\$269) of an air cleaner, was denied to the mother of an asthmatic child. This denial was based on a state regulation, which denied payment for items which were environmental control equipment, whose primary and customary use was nonmedical. After exhausting all levels of her administrative remedy, the mother resorted to the courts and eventually arrived in the New Jersey Supreme Court. *Dougherty* argued, in part, that the state regulation was inconsistent with the federal Social Security Act. The court’s reasoning rejecting this argument is compelling:

“Although Title XIX does not require states to provide funding for all medical treatment falling within the five general categories, it does require that ‘State medical plans establish “reasonable standards . . . for determining . . . the extent of medical

assistance under the plan which . . . are consistent with objectives of [Title XIX],” 42 U.S.C., § 1396a(a) (17) *Beal v. Doe*, 432 U.S. 438, 441, 97 S.Ct. 2366, 2369, 53 L.Ed.2d 464, 470 (1977). We have never held that our statutory program requires state reimbursement for all medically necessary services for every patient. *Monmouth Medical Center v. State*, 80 N.J. at 309, 403 A.2d 487 (footnote omitted) (1979).”

“There are two questions, then, in this case. Is the agency regulation valid, and was it correctly applied as to this claimant, i.e., was the order of waiver proper?

“In *Texter v. Dept. of Human Services*, 88 N.J. 376, 443 A.2d 178 (1982), we recently restated the principles governing review of agency regulations. We held there that ‘[a]dministrative agencies have wide discretion in selecting the means to fulfill the duties that the Legislature delegated to them.’ *Id.* at 383, 443 A.2d 178. N.J.S.A. 30:4D-5 and 4D-7 authorize the agency and the Commissioner to adopt rules and regulations to implement the policies of the act. On review, courts presume that an administrative regulation is valid. The burden is on the challenger to demonstrate that the regulation is arbitrary, capricious or unreasonable. *Aid D. v. Long* (1978) 75 N.J. 544, *New Jersey Guild of Hearing* 384 A.2d 795 (1978); *Cole Natl Corp. v. State Bd. of Exam. of Ophal. Disp.*, 57 N.J. 227, 231, 271 A.2d 421 (1970). A court will not substitute its judgment for the expertise of the agency. *New Jersey Guild*, *supra*, 75 N.J. at 562, 384 A.2d 795.

“In fulfilling its statutory mandate, the Division has adopted a comprehensive manual for the administration of the program. N.J.A.C. 10:49-1.1 *et seq.* Its several hundred pages give detailed descriptions of eligible items such as orthotic appliances, N.J.A.C. 10:55-1.1 *et seq.*, coverage for physical therapy, N.J. A.C. 10:53-1.6, and payment allowed for prescription

drugs. N.J.A.C. 10:51-6.18. In the subchapter entitled 'Medical Supplier Manual,' the agency specified certain noncovered items including personal incidentals, gauze, bandages, and orthopedic mattresses. N.J. A.C. 10:59-1.6. In subsection (a)(6) the following items were excluded from coverage:

“Environmental control equipment and supplies (for example, air conditioners, humidifiers, dehumidifiers, electrostatic filters and so forth: 1. exceptions are vaporizers and cool mist humidifiers.)

“The record does not disclose the reason for each exclusion. The agency argues that environmental equipment was excluded from coverage because it not only serves the medical needs of the patient but also aids the comfort and convenience of all of the members of the household. No one would deny that surgical gauze is necessary for medical treatment of a wound or that other appliances may be necessary for medical treatment, but an agency administering so vast and complex a program can well determine that such choices must be made and that certain items deserve different treatment. Judicial supervision of such classifications would be unwise. Establishment of priorities is best left to the legislative branch and executive agencies. Since the standards adopted were reasonable and consistent with the objectives of the Medicaid Act, the Appellate Division found that regulation to be valid. We agree.” (*Dougherty v. Human Services Dept.* (91 N.J. 1, 449 A.2d at 1238 (1982).)

The *Dougherty* Court specifically noted (in a footnote) that New Jersey did not violate section 440.220 in that it did not deny or exclude services on the basis of a specific condition. *Dougherty v. Human Services Dept.*, *supra*, 449 A.2d 1238, fn. 2. The court then went on to rule in *Dougherty's* favor on grounds unrelated to those at bar.

It is important to emphasize that the facts of *Dougherty* and the instant case were very similar. There was no exclusion from treatment of a specific medical condition. A comprehensive manual for administration of the program has been promulgated. The manual described objective criteria by which to measure a physical condition to ascertain if it is a medical necessity. Both state programs (New Jersey's and California's) were (and still are) vast and complex. No one in either case was denied vital services. In sum, the limitation in *Dougherty* and the limitation (pursuant to the current definition of medical necessity) in the case at bar were (not and are not) arbitrary or capricious.

California was empowered by 42 C.F.R. section 440.230(a)(2)(d) to place limitations on services based upon medical necessity. California had done exactly that. The promulgation of the current medical necessity definition had not rendered any medical service insufficient in amount, duration and/or scope so that it was unable to achieve its purpose.

In conclusion, California had done precisely what 42 C.F.R. section 440.230(a)(2)(d) permitted. Such action was consistent and compatible with the objectives of the Social Security Act.

The *Dougherty* court's analysis has been reflected or supported by federal cases. (*Curtis v. Taylor* (5th Cir. 1980) 625 F.2d 645; *Virginia Hospital v. Kenley* (1977) 427 F.Supp. 781.) This is the only analysis of 42 C.F.R. section 440.230 which gives meaning and harmonizes all of its language. This is precisely the sort of construction which the trial court erroneously did not utilize. (See

United States v. Menasche (1955) 348 U.S. 528; see also *Pinneke v. Preisser*, *supra*, 623 F.2d 546; *Rush v. Parham*, *supra*, 591 F.2d 121.)

In sum, the District Court of Appeals correctly interpreted the applicable case law. Its correct ruling should not be disturbed and the petition should be denied.

II

CALIFORNIA'S TAR SYSTEM IS LEGAL AND CONSISTENT WITH FEDERAL LAW

The trial court struck down California's entire prior authorization scheme. This scheme is implemented through the use of forms called Treatment Authorization Requests—TARS. It essentially held that the TAR system is an improper utilization control and so interferes with the relationship between the patient-recipient and the medical professional-provider that it is fatally inconsistent with the objectives of the federal Social Security Act. The Appellate Court corrected this fallacious conclusion and upheld California's prior authorization scheme.

This Court should also be mindful that, as previously demonstrated, the individual physician is not the sole arbiter of medical necessity.

This Court should lastly be mindful that the TAR process does not hinder emergency care; i.e., in emergencies, the provider does not need to satisfy the TAR procedure.

The federal government permitted states to "... place appropriate limits on a service based on ... utilization control procedures." (42 C.F.R. § 440.230(a)(2)(d).) The

long existing TAR system (Dr. Lackner testified that he used the TAR system when he was Director of the Department of Health; RT 245) is precisely that—a utilization control procedure.

Welfare and Institutions Code section 14133 provided:

“Utilization controls that may be applied to the services set forth in Section 14132 which are subject to utilization controls shall be limited to:

“(a) Prior authorization, which is approval by a department consultant, of a specified service in advance of the rendering of that service based upon a determination of medical necessity. Prior authorization includes authorization for multiple services which are requested and granted on the basis of an extended treatment plan where there is a need for continuity in the treatment of a chronic or extended condition.

“(b) Postservice prepayment audit, which is review for medical necessity and program coverage after service was rendered but before payment is made. . . .

“(c) Postservice postpayment audit, which is review for medical necessity and program coverage after service was rendered and the claim paid. . . .

“(d) Limitation on number of services, which means certain services may be restricted as a number within a specified time frame.

“(e) Review of services pursuant to Professional Standards Review Organization agreements entered into in accordance with Section 14104.”

California courts have not found any illegality in pertinent areas of California's prior authorization scheme. (*California Chiropractic Ass'n v. Human Relations Agency* (1979) 91 Cal.App.3d 141; see generally *Margulis v. Meyers* (1981) 122 Cal.App.3d 338.) This is especially noteworthy since Congress intended that states be given con-

siderable discretion and latitude in implementing their Medicaid plans. (*Dist. of Col. Pod. Soc. v. District of Columbia* (D.C. 1975) 407 F.Supp. 1259, 1263.)

Margulis is particularly instructive. The Court upheld a prior authorization scheme in the form of TARS which was imposed on the provider as a utilization control. This TAR scheme was required for all services rendered on behalf of all Medi-Cal patient-recipients. This approved TAR scheme was more stringent than the TAR scheme in use for the services disputed in the case at bar.

Respondent's evidence clearly established that the TAR system has been well established for numerous years, that it had previously been reviewed and approved by the federal government, that it had been continuously refined and tuned to provide expeditious, efficient and equitable service to the medical professional-provider and the patient-recipient, and that the federal government had indeed approved the current medical necessity definition and TAR scheme.

It must be emphasized that not all services require a TAR. (See *Margulis v. Meyers, supra*, 122 Cal.App.3d at 339.)

It is beyond peradventure that,

“... [w]here, as in the Medi-Cal program, limited funds are available, the imposition of more onerous restrictions upon provider services for those conditions which may generally be viewed as less life-threatening than those imposed with respect to the services of providers who do frequently deal with life-threatening situations, is clearly supported by a rational basis.” (*California Chiropractic Ass'n v. Human Relations Agency, supra*, 91 Cal.App.3d at 150.)

Respondent's evidence clearly established the many efforts made to reduce any inconvenience. California's utilization controls were inarguably necessary, plainly efficient and patently legal. The Appellate Court correctly recognized this fact in its opinion. That opinion should not be disturbed. The Petition for Writ of Certiorari should be denied.

CONCLUSION

For the foregoing reasons this Court should deny the Petition for Writ of Certiorari. The California appellate opinion is a correct statement of the law. No further review should occur.

DATED: July, 1987.

Respectfully submitted,

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